



## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1266]

### **Certain Wearable Electronic Devices with ECG Functionality and Components Thereof**

### **Notice of the Commission's Final Determination Finding a Violation of Section 337;**

### **Issuance and Suspension of a Limited Exclusion Order and a Cease and Desist Order;**

### **Termination of the Investigation**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined that there is a violation of section 337 in the above-captioned investigation. The Commission has further determined to issue a limited exclusion order and a cease and desist order and to set a bond in the amount of \$2 per unit of covered articles imported or sold during the period of Presidential review. The enforcement of these orders, including the bond provision, is suspended pending final resolution of the U.S. Patent and Trademark Office, Patent Trial and Appeal Board’s (“PTAB”) Final Written Decisions finding the asserted patent claims unpatentable.

**FOR FURTHER INFORMATION CONTACT:** Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3042. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email [EDIS3Help@usitc.gov](mailto:EDIS3Help@usitc.gov). General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal, telephone (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** On May 26, 2021, the Commission instituted this investigation based on a complaint filed by AliveCor, Inc. of Mountain View, California (“AliveCor”). 86 FR 28382 (May 26, 2021). The complaint alleged violations of section 337 based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain wearable electronic devices with ECG functionality and components thereof by reason of infringement of one or more of claims 1-30 of U.S. Patent No. 10,595,731 (“the ’731 patent”); claims 1-23 of U.S. Patent No. 10,638,941 (“the ’941 patent”); and claims 1-4, 6-14, 16-20 of U.S. Patent No. 9,572,499 (“the ’499 patent”). *Id.* The Commission’s notice of investigation named Apple Inc. of Cupertino, California (“Apple”) as the sole respondent. The Office of Unfair Import Investigations (“OUII”) is named as a party in this investigation. *Id.*

On February 23, 2022, the ALJ issued an initial determination granting AliveCor’s motion to terminate the investigation as to (1) claims 1-4, 6-14, and 18-20 of the ’499 patent; (2) claims 2, 4, 6, 7, 11, 13, 14, and 17-30 of the ’731 patent; and (3) claims 1-11, 14, 15, 17, and 18 of the ’941 patent based upon withdrawal of allegations from the complaint as to those claims. Order No. 16 (Feb. 23, 2022), *unreviewed by* Notice (Mar. 18, 2022).

On June 27, 2022, the ALJ issued the final initial determination (“ID”) finding a violation of section 337 as to the ’941 and ’731 patents, and no violation of section 337 as to the ’499 patent. The ID found that the parties do not contest personal jurisdiction and that the Commission has *in rem* jurisdiction over the accused products. ID at 18. The ID further found that the importation requirement under 19 U.S.C. 1337(a)(1)(B) is satisfied. *Id.* (citing CX-0904C (Apple stipulating that it imports the accused products into the United States)). Regarding the ’941 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 12, 13, 19, and 20-23, and that Apple failed to show that any of the asserted claims are invalid. *Id.* at 30-45, 60-98. For the ’731 patent, the ID found that AliveCor has proven infringement of the asserted claims, claims 1, 3, 5, 8-10, 12, 15, and 16, but that Apple

has proven that claims 1, 8, 12, and 16 are invalid for obviousness. *Id.* at 105-108, 113-127. For the '499 patent, the ID found that AliveCor failed to prove infringement of the asserted claims, claims 16 and 17, and that claim 17 is invalid for lack of patentable subject matter under 35 U.S.C. 101. *Id.* at 129-138, 140-152. Finally, the ID found that AliveCor has proven the existence of a domestic industry that practices the asserted patents as required by 19 U.S.C. 1337(a)(2). *Id.* at 152-183. The ID included the ALJ's recommended determination on remedy and bonding ("RD"). The RD recommended that, should the Commission find a violation, issuance of a limited exclusion order and a cease and desist order would be appropriate. ID/RD at 190-193. The RD also recommended imposing no bond for covered products imported during the period of Presidential review. ID at 193-95.

On July 11, 2022, Apple filed a petition for review of the ID, and AliveCor filed a combined petition and contingent petition for review of the ID. On July 19, 2022, the private parties and OUII's investigative attorney filed responses to the petitions.

On September 22, 2022, the Commission determined to review the final ID in part. 87 Fed. Reg. 58819-21 (Sept. 28, 2022). Specifically, the Commission determined to review the final ID's invalidity findings, including patent eligibility under 35 U.S.C. 101 and obviousness under 35 U.S.C. 103, and the economic prong of the domestic industry requirement for all three patents. *Id.* The Commission requested briefing from the parties on certain issues under review. The Commission requested briefing from the parties, interested government agencies, and interested persons on remedy, the public interest, and bonding. *Id.*

On October 6, 2022, the parties filed initial submissions in response to the Commission's request for briefing. On October 14, 2022, the parties filed reply submissions. On October 21, 2022, Apple moved for leave to file a sur-reply to AliveCor's reply submission. On October 24, 2022, AliveCor filed an opposition. OUII filed a response in opposition on November 2, 2022.

The Commission has determined to deny Apple's motion for leave to file a sur-reply to AliveCor's reply submission.

On December 7, 2022, Apple filed an emergency motion, asking “the Commission to suspend any remedial orders or, in the alternative, extend the December 12, 2022 Target Date of its Final Determination and stay all proceedings prior to issuance of any Final Determination pending final resolution of any appeal of the PTAB’s decisions” finding the asserted patent claims unpatentable. Apple Emergency Motion at 1. On December 9, 2022, AliveCor filed an opposition to Apple’s motion. On December 16, 2022, OUII filed a response in support of Apple’s motion, but only to the extent that any remedy the Commission issues be suspended pending appeal of the PTAB decisions. OUII Reply to Emergency Motion at 4.

Upon review of the parties’ submissions, the ID, the RD, evidence of record, and public interest filings, the Commission has determined that Apple violated section 337 by reason of importation and sale of articles that infringe asserted claims 12, 13, and 19-23 of the ’941 patent; and claims 1, 3, 5, 8-10, 12, 15, and 16 of the ’731 patent. Regarding the issues under review, the Commission has determined to affirm the ID’s economic prong of the domestic industry findings with the modifications described in the accompanying Commission opinion. Concerning invalidity, the Commission has determined to affirm the ID’s patent eligibility findings under 35 U.S.C. 101 as to one claim with modifications explained in the Commission opinion and reverse as to another; and to correct the ID for not considering objective indicia of non-obviousness for certain asserted claims. For remedy, the Commission has determined to issue a limited exclusion order prohibiting further importation of infringing products and a cease and desist order against Apple. The Commission has determined that the public interest factors do not counsel against issuing remedial orders. The Commission has determined that a bond in the amount of \$2 per unit of covered articles is required for covered products imported or sold during the period of Presidential review.

The enforcement of these orders, including the bond provision, is suspended pending final resolution of the PTAB’s Final Written Decisions finding the asserted patent claims unpatentable. *See* 35 U.S.C. 318(b); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00971, Patent

10,595,731, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00972, Patent 10,638,941, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022).

The Commission's vote on this determination took place on December 22, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Issued: December 22, 2022.

**Katherine Hiner,**  
*Acting Secretary to the Commission.*

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